

K091302
DEC - 4 2009

510(K) SUMMARY

Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Marilyn Konicky
Director, Regulatory Affairs
(609) 936-5563

Date: November 30, 2009

Name of the device:

Proprietary Name: Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels
Bone Void Filler
Common Name: Filler, Bone Void, Calcium Compound, Product Code MQV
Classification Name: Class II
Regulation Number 888.3045
Orthopedic

Classification Panel:

Substantial Equivalence:

Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels are substantially equivalent in function and intended use to the currently marketed Integra MOZAIK Osteoconductive Scaffold - Putty (K062353).

Intended Use:

Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels combined with bone marrow aspirate, are intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine (posterolateral spinal fusions only), and pelvis not intrinsic to the stability of the bony structure. Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels are also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels are resorbed and replaced with bone during the healing process.

Device Description:

The Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels are resorbable bone void fillers made from a porous highly purified collagen matrix that has high purity beta tricalcium phosphate (β -TCP) granules and cubes dispersed throughout. The implant is provided sterile, non-pyrogenic, for single use in double peel packages.

The Integra Mozaik Moldable Morsels and Integra Moldable Morsels bone grafting construct are designed to facilitate the repair of bony defects. In the dry state, the matrix has a three dimensional trabecular network of pores that resembles the pore structure of human cancellous bone. The Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels quickly imbibe fluids, making it easy to combine with bone marrow aspirate.

Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels guide the regeneration of bone across the defect site into which the Moldable Morsels are implanted. New bone forms in apposition to the matrix surface when the graft is placed in direct contact with viable host bone. Ultimately the matrix is resorbed and remodeled into bone.

Conclusion:

Valid scientific evidence through physical property testing provide reasonable assurance that Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels are safe and effective under the proposed conditions of use, and are, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
% Mr. Peter Allan
Regulatory Affairs Project Manager
311 Enterprise Drive
Plainsboro, New Jersey 08536

DEC - 4 2009

Re: K091302

Trade/Device Name: Integra Mozaik Moldable Morsels and
Integra OS Moldable Morsels
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: November 05, 2009
Received: November 06, 2009

Dear Mr. Allan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

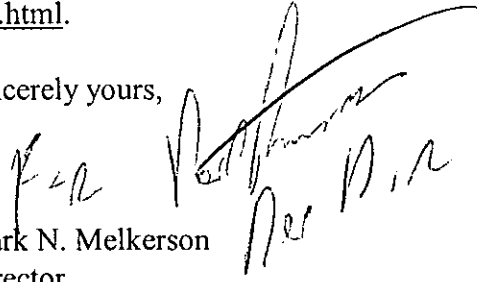
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: **K091302**

Device Name: Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels

Indications for Use:

The Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels, combined with bone marrow aspirate, are intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine (posterolateral spinal fusions only), and pelvis not intrinsic to the stability of the bony structure. Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels are also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), Integra Mozaik Moldable Morsels and Integra OS Moldable Morsels are resorbed and replaced with bone during the healing process.

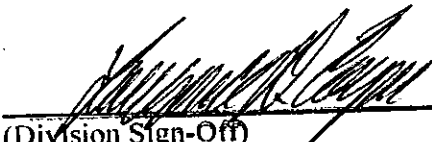
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 FOR M. MELKERSEN
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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